

AMENDED IN SENATE MARCH 17, 2010

**SENATE BILL**

**No. 975**

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**Introduced by Senator Price**

February 8, 2010

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An act *to amend Section 1635 of*, to add Section 1643.3 to, and to repeal and add Section 1639.01 of, the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL'S DIGEST

SB 975, as amended, Price. Tissue bank licensing.

Existing law requires the State Department of Public Health to establish regulations, as specified, governing the operation and maintenance of tissue banks licensed in California. Existing law allows for the revocation or suspension of a tissue bank's license for specified reasons. Violation of these provisions is a misdemeanor.

This bill would require the collection, processing, storage, or distribution of human tissue for use in California to comply with the 12<sup>th</sup> edition of Standards for Tissue Banking *in effect on January 1, 2011*, as published by the American Association of Tissue Banks, and would require *the department to evaluate* future amendments of these standards ~~to be adopted~~ *determine which changes to adopt* as regulations, ~~if approved by the department~~. This bill would also allow the department to impose on licensed tissue banks, as an alternative to suspension or revocation of a tissue bank's license, a civil administrative penalty of \$100 per day of noncompliance per violation not to exceed an aggregate of \$3,000 ~~per day~~.

*Existing law defines "tissue" as any human cell, group of cells, tissue, or organ, giving specific examples.*

*This bill would delete organ from this definition.*

Because the bill would make changes to the definition of a crime, it ~~constitutes~~ *would impose* a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1     **SECTION 1.** *Section 1635 of the Health and Safety Code is*  
2 *amended to read:*

3     1635. (a) “Donor” is an individual, living or deceased, from  
4 whom tissue is removed.

5     (b) “Person” is an individual, corporation, business trust, estate  
6 trust, partnership, association, state or local government, or  
7 subdivision or agency thereof, or any other legal entity.

8     (c) “Tissue” is any human cell, group of cells, ~~tissue or organ~~  
9 *or tissue* including the cornea, sclera, or vitreous humor and other  
10 segments of, or the whole eye, bones, skin, arteries, sperm, blood,  
11 other fluids, and any other portion of a human body.

12     (d) “Tissue bank” is any place, establishment, or institution that  
13 collects, processes, stores, or distributes tissue for transplantation  
14 into human beings.

15     (e) “Transplantation” is the act or process of transferring tissue,  
16 including by ingestion, from a donor to the body of the donor or  
17 another human being.

18     (f) “State department” is the State Department of *Public Health*  
19 ~~Services~~.

20     ~~SECTION 1.~~

21     **SEC. 2.** *Section 1639.01 of the Health and Safety Code is*  
22 *repealed.*

23     ~~SEC. 2.~~

24     **SEC. 3.** *Section 1639.01 is added to the Health and Safety*  
25 *Code, to read:*

26     1639.01. (a) Notwithstanding Section 1639, no person shall  
27 engage in the collection, processing, storage, or distribution of  
28 human tissue unless the tissue is collected, prepared, labeled,

1 stored, and distributed in accordance with the standards set forth  
2 in the 12th edition of Standards for Tissue Banking *in effect on*  
3 *January 1, 2011*, as published by the American Association of  
4 Tissue Banks and in effect on May 1, 2008.

5 ~~(b) Amendments to, or later editions of, the Standards for Tissue~~  
6 ~~Banking shall be adopted as regulations, upon approval of the~~  
7 ~~department, not later than 90 days after publication. This section~~  
8 ~~shall not be subject to the rulemaking requirements of Chapter 3.5~~  
9 ~~(commencing with Section 11340) of Part 1 of Division 3 of Title~~  
10 ~~2 of the Government Code.~~

11 *(b) Consistent with the purposes of this chapter, the department*  
12 *shall evaluate amendments to the standards made in subsequent*  
13 *editions by the American Association of Tissue Banks to determine*  
14 *which changes to adopt as revised regulations. Proposed changes*  
15 *to the regulations shall be posted on the department's Internet*  
16 *Web site at least 45 days prior to their adoption. Public comment*  
17 *shall be accepted by the department for at least 30 days after each*  
18 *posting. If a member of the public requests a public hearing during*  
19 *the 30-day-posting period, the hearing shall be held prior to the*  
20 *adoption of the proposed changes. Comments received shall be*  
21 *considered prior to the posting of final changes. Adoption of*  
22 *changes by the department pursuant to this section shall,*  
23 *notwithstanding any other provision of law, not be subject to the*  
24 *rulemaking requirements of Chapter 3.5 (commencing with Section*  
25 *11340) of Part 1 of Division 3 of Title 2 of the Government Code*  
26 *and written responses to public comments shall not be required.*

27 ~~SEC. 3.~~

28 *SEC. 4.* Section 1643.3 is added to the Health and Safety Code,  
29 to read:

30 1643.3. As an alternative to revocation or suspension of a  
31 license issued under this chapter, the department may impose an  
32 alternative civil administrative penalty of one hundred dollars  
33 (\$100) per day of noncompliance per violation, including an  
34 immediate jeopardy violation, except that the aggregate penalty  
35 ~~per day~~ shall not exceed three thousand dollars (\$3,000). This  
36 penalty may be imposed only after notice and an opportunity to  
37 respond in accordance with Section 100171.

38 ~~SEC. 4.~~

39 *SEC. 5.* No reimbursement is required by this act pursuant to  
40 Section 6 of Article XIII B of the California Constitution because

1 the only costs that may be incurred by a local agency or school  
2 district will be incurred because this act creates a new crime or  
3 infraction, eliminates a crime or infraction, or changes the penalty  
4 for a crime or infraction, within the meaning of Section 17556 of  
5 the Government Code, or changes the definition of a crime within  
6 the meaning of Section 6 of Article XIII B of the California  
7 Constitution.

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